UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

KABCO PHARMACEUTICALS, INC., a/k/a KABCO, INC., a corporation, and ABU KABIR, an individual,

Defendants.

COMPLAINT FOR PERMANENT INJUNCTION

Civil Action No. CV-12 3468

BIANCO, J.

BOYLE, M

SUMMONS ISSUED

Plaintiff, the United States of America, by Loretta E. Lynch, United States Attorney for the Eastern District of New York, respectfully represents to this Honorable Court as follows:

INTRODUCTION

1. This action is brought by the United States of America pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the equitable authority of this Court, to enjoin and restrain Kabco Pharmaceuticals, Inc., a/k/a Kabco Inc., a corporation ("Kabco"), and Abu Kabir, an individual (collectively, "Defendants"), from violating:

a. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

b. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Kabco is a New York corporation with its principal place of business at 2000 New Horizons Boulevard, Amityville, New York 11701 ("the Facility"), within the jurisdiction of this Court.

5. Individual Defendant Abu Kabir is the Chief Executive Officer and President of Kabco.

6. Defendant Kabir is responsible for all Kabco's business operations, and he oversees all aspects of the company. Defendant Kabir has the duty to prevent, detect, and correct violations of the Act and the authority to hire and fire employees. Defendant Kabir performs his duties at the Facility, within the jurisdiction of this Court.

7. Defendants have been, and are now engaged in, manufacturing, preparing, packaging, labeling, packing, holding, and distributing "dietary supplements" within the meaning of 21 U.S.C. § 321(ff). Such products include, but are not limited to, Brewers Yeast Tablets, Dandelion Root Capsules, Night-Time Herb Capsules, Inositol Calcium & Magnesium Capsules, Vitamin C-500 With Rose Hips Time Released Tablets, and Joint All Capsules.

8. Defendants regularly manufacture dietary supplements using components, such as passion extract, rice flour, and dandelion root that they receive from outside New York. Defendants also introduce, or deliver for introduction, finished dietary supplements into interstate commerce.

DEFENDANTS ADULTERATE THEIR DIETARY SUPPLEMENTS

9. The United States Food and Drug Administration ("FDA") inspected Defendants' facility between September 28 and October 21, 2011. This inspection established that the dietary supplements that Defendants manufacture and distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not comply with the current good manufacturing practice ("cGMP") regulations for dietary supplements set forth at 21 C.F.R. Part 111.

10. Manufacturing in compliance with cGMP means that the manufacturer incorporates a set of controls in the design and production processes to consistently ensure a quality, finished product. Dietary supplements not prepared, packed, or held in conformance with cGMP are deemed adulterated. 21 U.S.C. § 342(g)(1).

11. During the September-October 2011 inspection, FDA investigators documented numerous deviations from cGMP. These deviations include, but are not limited to, the following:

a. Defendants failed to follow a written master manufacturing record ("MMR") for each unique formulation of dietary supplement that they manufacture, and for each batch size, to ensure batch to batch uniformity, in violation of 21 C.F.R. § 111.205(a);

b. Defendants failed to ensure that their quality control operations for the MMR, batch production record, and manufacturing operations include reviewing all monitoring required as part of their production and process control system, in violation of 21 C.F.R. § 111.123(a)(3);

c. Defendants' quality control personnel failed to reject dietary supplements that did not meet established product specifications, in violation of 21 C.F.R. § 111.77(a);

d. Defendants failed to review and investigate product complaints, in violation of 21 C.F.R. § 111.560;

e. Defendants failed to include all the required information in the MMR, including procedures for sampling and a cross-reference to procedures for tests or examinations,

in violation of 21 C.F.R. § 111.210(h)(2);

f. Defendants failed to identify and use an appropriate scientifically valid method for each established specification for which testing or examination is required to determine whether the specification is met, in violation of 21 C.F.R. § 111.320(b);

g. Defendants failed to hold components, dietary supplements, packaging, and labels under conditions that do not lead to the mixup, contamination, or deterioration of components, dietary supplements, packaging, and labels, in violation of 21 C.F.R. § 111.455(c); and

h. Defendants failed to keep written records required under 21 C.F.R. Part 111, namely MMRs, for at least one year past the dietary supplement's shelf life date, in violation of 21 C.F.R. § 111.605(a).

12. The cGMP deviations documented during FDA's September-October 2011 inspection establish that Defendants' dietary supplements are adulterated within the meaning of 21 U.S.C. § 342(g)(1).

13. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1).

14. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

15. Defendants' adulteration of dietary supplements led to a recent recall of their products. On October 6, 2011, Defendants recalled Brewers Yeast Tablets, which were manufactured in violation of cGMP and contained an undeclared milk allergen. In a letter to FDA, dated November 14, 2011, Defendant Kabir "acknowledge[d] the seriousness" of "the addition of an undeclared allergen material in [Defendants'] product" and admitted that the

presence of Whey Polio in the product "may have resulted [in] serious health hazards to consumers."

DEFENDANTS' HISTORY OF VIOLATIONS

16. Defendants are well aware, and acknowledge, that their operations violate the law and that their failure to cease their violative conduct and implement corrections could lead to regulatory action.

17. FDA inspected Defendants' facility between May 3 and 18, 2011, and between June 21 and July 7, 2010. During both inspections, FDA observed significant violations of the Act and cGMP. During these inspections, the FDA investigators found some of the same and similar violations as those observed during the September-October 2011 inspection of the Facility, including but not limited to violations involving: MMR requirements (21 C.F.R. § 111.210); batch record requirements (21 C.F.R. § 111.260); requirements applicable to holding components, dietary supplements, packaging, and labels (21 C.F.R. § 111.455); and quality controls (21 C.F.R. § 111.110).

18. At the conclusion of the May 2011 and June-July 2010 inspections, the FDA investigators issued to Defendant Kabir a List of Inspectional Observations ("Form FDA 483"), detailing Defendants' numerous violations of the Act and cGMP, and discussed the documented observations with him.

19. Kabco submitted written responses dated November 14, 2011, June 7, 2011, and July 21, 2010, to the Forms FDA 483 issued following the September-October 2011, May 2011, and June-July 2010 FDA inspections, respectively. In the written responses, Defendants acknowledged their violative conduct and promised to immediately implement corrections.

20. On November 10, 2010, FDA issued a Warning Letter to Defendant Kabir, informing him that the significant cGMP violations that FDA documented during the June-July 2010 inspection rendered Defendants' dietary supplements adulterated under the Act. The Warning Letter further cautioned Defendants that their failure to promptly correct the violations,

and prevent future ones, could lead to additional regulatory action, including an injunction of their operations.

21. Defendants responded to the Warning Letter, by letter dated December 3, 2010. Defendant Kabir acknowledged the firm's violations and promised that Defendants would achieve full cGMP compliance. On February 8, 2011, FDA notified Defendants that they had failed to satisfactorily address the violations noted in the Warning Letter, and informed Defendants that FDA would evaluate any future corrections during FDA's next inspection. As discussed above, FDA since conducted two inspections in May 2011 and September-October 2011, and both revealed new and recurrent violations of the Act and cGMP.

22. Based on their repeated course of conduct, Defendants, unless restrained by order of this Court, will continue to violate 21 U.S.C. §§ 331(a) and (k) and threaten the public health.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them, cease manufacturing, preparing, processing, packaging, packing, labeling, holding, and/or distributing dietary supplements at or from the Facility or at or from any other location(s) at which Defendants manufacture, prepare, process, package, pack, label, hold, and/or distribute dietary supplements, now or in the future, unless and until Defendants bring their manufacturing, preparing, processing, packaging, packing, labeling, holding, and/or distributing operations into compliance with the Act and cGMP;

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them, be permanently restrained and enjoined, under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate

commerce, dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

B. Violating 21 U.S.C. § 331(k), by causing dietary supplements to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the manufacturing, preparing, processing, packaging, packing, labeling, holding, and distribution of all of Defendants' dietary supplements to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Dated this 13th day of July, 2012.

Respectfully submitted,

LORETTA E. LYNCH
United States Attorney

By: Thomas A. McFarland
Thomas A. McFarland
Assistant U.S. Attorney
U.S. Attorney's Office
610 Federal Plaza, 5th Floor
Central Islip, NY 11722

MICHAEL S. BLUME
Director

By: /s/ Lauren H. Bell
Lauren H. Bell
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
Tel. (202) 353-1991

Fax (202) 514-8742

Of Counsel:

WILLIAM B. SCHULTZ
Acting General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel for Litigation

MELISSA J. MENDOZA
Associate Chief Counsel for Enforcement
United States Department of Health and
Human Services